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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/625,751	07/26/2000	Mary M. Morris	11738.00002	8051

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EXAMINER
SERKE, CATHERINE

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/625,751	MORRIS ET AL.	
	Examin r	Art Unit	
	Catherine Serke	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *31 and 32* is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-6, 8, 11-12, 16-17, 19-21, 23-24 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Brucker et al (US Pat# 5,462,521).

Brucker discloses a perfusion tip for a catheter that includes a proximal end having an opening, a distal end defining at least one opening, a drug delivery segment with a longitudinal axis and a length of about 0.1-1.0 cm (see figure 9). The segment has an outside surface with an outside diameter of about 0.64 inches and an inside surface with an inside diameter of about 0.32 inches. The segments has non-tapered tubes having a length of about 0.16 inches that extend radially from the inside surface of the outside surface where the ratio of the length of the tubes to the diameter of the tubes is about 5-25. The segment defines a lumen along its longitudinal axis. The tubes are arranged in a row parallel with the longitudinal axis of the segment and there is at least a proximal tube a middle tube and a distal tube within the row. The tubes are equally spaced from each other in the row. The distance from the proximal tube to the distal tube in the row is about 5.5 mm and the distance from the middle tube to the distal end of the lumen of the segment is about 5 mm. The tubes have substantially the same diameters and range in diameter size from about 0.001 to 0.005 inches. The segment has ring bands (30) that may be made from platinum or stainless steel. The catheter is capable of being implantable for more than 24 hours,

and is capable of providing fluid containing a therapeutic drug to the target site at a rate of about 2 microliter/hour to 10 microliters/minute. The fluid is considered a therapeutic drug in that it regulates the impedance rise of tissue in contact with the catheter tip and a fluid source is considered inherent for the device to function as disclosed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4, 7, 9-10, 12-15, 18, 25-27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brucker et al.

Regarding claim 25, Brucker meets the claim limitations as described above but fails to include a method including forming the segment, forming the tubes, providing a therapeutic compound and distributing the compound. The fluid is considered a therapeutic drug in that it regulates the impedance rise of tissue in contact with the catheter tip. At the time of the invention, it would have been obvious to have carried out the method steps as described above since the steps would have been required to assemble and use the device.

Regarding claims 4 and 27, Brucker meets the claim limitations as described above but fails to include laser or ion beam drilled tubes. At the time of the invention, it would have been obvious to manufacture the tubes using laser or ion beam drilling since it is well known in the art and is used in order to provide enhanced accuracy regarding manufacturing tolerances.

Regarding claims 7, 10, 13 and 18, Brucker meets the claim limitations as described above but fails to disclose the number of tubes as claimed. At the time of the invention, it would have been obvious to have the number of tubes as claimed since perfusion cannula are well known in the art to have a variety of perfusion ports (tubes) depending on the size of the tissue being treated. Adding more tubes to the invention of Brucker would have been done in order to provide greater perfusion to a larger tissue bed.

Regarding claims 9-10, 12 and 14-15, Brucker meets the claim limitations as described above but fails to disclose 4 or 8 rows. At the time of the invention, it would have been obvious to have the number of rows as claimed since perfusion cannula are well known in the art to have a variety of perfusion port arrangements depending on the size of the tissue being treated. Adding more rows to the invention of Brucker would have been done in order to provide greater perfusion to a larger tissue bed.

Claims 22 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brucker in view of Lindsay et al (US Pat# 4,863,441).

Brucker meets the claim limitations as described above but fails to include the tubes being tapered.

Lindsay discloses a venous return cannula that has ports at the distal end that are chamfered (tapered) in order to provide resistance to kinking at the tip.

At the time of the invention, it would have been obvious to incorporate the teaching of chamfered (tapered) ports or tubes of Lindsay into the invention of Brucker in order to provide enhanced resistance to bending.

Allowable Subject Matter

Claims 31-32 are allowed.

Response to Arguments

Applicant's arguments filed 9/30/02 have been fully considered but they are not persuasive.

Regarding applicant's argument that Brucker does not teach a drug delivery segment that provides fluid containing a therapeutic drug to a target site at a rate of about 2 microliter/hour to 10 microliters/min, the prior art meets the structural limitations of the claims. The examiner reminds applicant that functional language is given limited patentable weight. As long as a prior art reference, while meeting the structural limitations of the claimed device, is capable of accomplishing the recited function, then the claimed device does not overcome the cited prior art. The Brucker device is capable of performing the claimed function since the prior art has the structure of the claimed device and therefore can function as the claimed device due to its same structure. Furthermore, the fluid used to protect the tip is considered a therapeutic/drug since the fluid is used to regulate the impedance rise of tissue in contact with the catheter tip.

Regarding applicant's argument that Brucker does not teach a ratio of the length of the tubes to the diameter of the tubes, while Brucker does not have a specific length disclosed the figures are considered part of the disclosure and from those the ratio can be ascertained. If one looks to figure 9 and determines the ratio of the length of the tubes to the width, the ratio is about

5. The examiner would also like to mention that the claim language states "**about** 5-25" [emphasis added] which in itself is imprecise and broad.

Regarding applicant's argument that Brucker does not teach "substantially equal flow through each of the tubes", attention is drawn to column 6 line 23-27 of the specification. The disclosure states "[I]n these embodiments, channels 56,58 are designed to communicate with path means 54 to provide a continuous, evenly distributed fluid protective layer...". Evenly distributed and substantially equal flow imparts the same function.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine Serke whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke
December 16, 2002

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700